UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, -against- B4B EARTH TEA LLC, a limited liability company; B4B CORP., a corporation; and ANDREW MARTIN SINCLAIR, individually and as an officer of B4B EARTH TEA LLC and B4B CORP., Defendants.	MEMORANDUM & ORDER 22-CV-1159 (ENV) (RML)

VITALIANO, D.J.

On March 3, 2022, the government commenced this action against defendants B4B Earth Tea LLC, B4B Corp. (collectively, "B4B"), and B4B's sole founder, owner, and/or officer, Andrew Martin Sinclair, alleging that defendants deceptively advertised and misrepresented their herbal tea product and continue to introduce the product into interstate commerce in violation of the Federal Trade Commission Act ("FTCA"), 15 U.S.C. §§ 45(a), 45(m)(1)(A), 52, and 57a(a)(1)(B), the COVID-19 Consumer Protection Act ("CCPA"), Pub. L. No. 116-260, Title XIV, § 1401(b)(1), and the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 331(d). *See* Compl., Dkt. 1. The government seeks, *inter alia*, a permanent injunction barring defendants from continuing to deceptively market, advertise, and sell the product. Sinclair now moves to dismiss the government's claims.[1]

[1] On June 1, 2022, Sinclair noticed two motions to dismiss, with one purportedly filed under Rule 12 and the other under Rule 11. *See* Rule 12 Motion, Dkt. 12; Rule 11 Motion, Dkt. 13. Construing

Background

Sinclair created and manufactured an herbal tea product called B4B Earth Tea Extra Strength ("Earth Tea"), which he sells through B4B's website for $60 per 16-ounce bottle. Compl. at ¶¶ 1, 10, 23. Since at least April 2020, Sinclair has marketed Earth Tea on the internet and across various social media platforms as preventing, treating, and curing COVID-19. *Id.* ¶¶ 1, 10, 24.

Illustrative of defendant's claims about Earth Tea's efficacy include his posting on social media that Earth Tea is "guaranteed" to get consumers out of quarantine within twenty-four hours. *Id.* ¶ 26. Defendant has additionally claimed that Earth Tea is the "most effective [t]reatment against" COVID-19, even moreso than the government-issued vaccines, and that Earth Tea is "100% effective with 0 [s]ide effects." *Id.* ¶¶ 26, 29, 30. Significantly, prior to its first offering for sale and continuing through the date this lawsuit was filed, the government represents that there were no published reports or other evidence of any human clinical study substantiating defendant's claims about Earth Tea. *Id.* ¶ 27. Despite this, Sinclair has made numerous claims that Earth Tea is backed by scientific data.[2] *Id.* ¶¶ 27–29.

On February 18, 2021, the Federal Trade Commission ("FTC") and Food and Drug

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the filings liberally, they will be considered together as a single motion to dismiss pursuant to Rule 12(b)(6). Additionally, following the filing of the motions, counsel for the defendants withdrew. *See* Dkt. 20. Sinclair was advised that, while the personal claims could proceed *pro se*, the corporate claims could not proceed without counsel. *See* Order dated June 18, 2023. Sinclair informed the Court by letter that he was unable to obtain counsel, would proceed *pro se* in his individual capacity, and would allow the claims against B4B to default. Letter, Dkt. 33.

[2] For example, in videos posted to YouTube, Sinclair claimed that forty-eight people who tested positive for COVID-19 bought Earth Tea, drank half of the bottle cold and half of the bottle hot before bedtime, and woke up without symptoms. *Id.* ¶ 26. Further, B4B's website describes a July 2021 clinical study conducted in India consisting of a single group of fifteen adults with "mild COVID-19" who took two 8-ounce doses of Earth Tea and were evaluated for symptoms four to five days later. *Id.* ¶¶ 28–29. Sinclair claimed that the study resulted in a finding of "statistically significant efficacy" of Earth Tea, with "a significant result in RT-PCR lab testing." *Id.*

Administration ("FDA") jointly issued a warning letter to B4B Corp. that its advertising on its website and Twitter account unlawfully marketed Earth Tea with respect to COVID-19. *Id.* ¶ 36. Specifically, the letter stated that "[i]t is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product . . . can prevent, treat, or cure human disease" without "competent and reliable scientific evidence" to substantiate the claims. *Id.* The letter indicated that there was no known study corroborating the claims about Earth Tea's efficacy in treating COVID-19. *Id.* The letter further identified Earth Tea as an "unapproved new drug" and "misbranded drug," and warned defendant that failure to cease its violative behaviors would result in legal action. *Id.* ¶ 37. On February 19, 2021, Sinclair responded and removed from B4B's website claims about Earth Tea's ability to treat and cure COVID-19. *Id.* ¶ 38. The FTC and FDA sent another letter in March 2021, acknowledging that Sinclair addressed the violations identified in the previous letter and notifying him of his continuing responsibility to comply with the law. *Id.*

However, in April 2021, Sinclair resumed making claims about Earth Tea's efficacy against COVID-19. *Id.* ¶ 39. On September 29, 2021, FTC staff informed him by e-mail that his claims violated the FTCA and CCPA. *Id.* Despite this warning, Sinclair continued making claims about Earth Tea. *Id.* As of the filing of the complaint, Sinclair was still distributing Earth Tea. *Id.* ¶ 40.

On June 1, 2022, Sinclair contemporaneously filed two motions directed at the complaint which, as previously indicated, the Court construes as a unitary Rule 12(b)(6) motion to dismiss. The first of the motions argues that Earth Tea is a dietary supplement and not a drug. Rule 12 Mot. at 2.[3] The second seeks to strike paragraphs of the complaint that wrongly charge Sinclair

[3] All citations to pages of the parties' briefing refer to the Electronic Case Filing System ("ECF") pagination.

with deception and fraud. Rule 11 Mot. at 2.

Legal Standard

To survive a Rule 12(b)(6) motion, the complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)). This "plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556). When considering a Rule 12(b)(6) motion, a court "must accept as true all allegations in the complaint and draw all reasonable inferences in favor of the non-moving party." *Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co.*, 517 F.3d 104, 115 (2d Cir. 2008) (quoting *Gorman v. Consol. Edison Corp.,* 488 F.3d 586, 591–92 (2d Cir. 2007)).

Discussion

I. Exemption From FDCA

In deference to Sinclair's *pro se* status, the Court construes his motion, as it must, to raise the strongest argument that it suggests, *see In re Sims*, 534 F.3d 117, 133 (2d Cir. 2008), which, in this case, is that Earth Tea is a dietary supplement and therefore is exempt from regulation as a drug under the FDCA. Rule 12 Mot. at 2. The motion argues that four facts about the regulation of dietary supplements listed on the FDA's website apply to Earth Tea; namely: (1) "[d]ietary supplement manufacturers do not have to get [FDA] approval before producing or selling these products"; (2) "[f]ederal law does not require dietary supplements to be proven safe to FDA's satisfaction before they are marketed"; (3) "[f]or most claims made in the labeling of dietary supplements, the law does not require the manufacturer or seller to prove to FDA's satisfaction

that the claim is accurate"; and (4) "[d]ietary supplements are regulated by the FDA as food, not as drugs." *Id.*

Sinclair's argument does not square well with the foundational reach of the federal regulation of drugs. Calling a substance a dietary supplement does not automatically create an escape hatch from drug regulation. Indeed, the FDCA's definition of a "drug" includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1); *see also* Compl. ¶ 18. Intended use "refer[s] to the objective intent of the persons legally responsible for the labeling of an article." 21 C.F.R. § 201.128. Objective intent may be shown by, *inter alia*, "labeling claims, advertising matter, or oral or written statements by such persons." *Id.*

Here, the government alleges that defendant created, promoted, and marketed Earth Tea as a treatment for COVID-19. Compl. ¶¶ 1, 10, 24, 26–31. Through social media statements, Sinclair represented that Earth Tea is a "proven natural treatment for COVID-19" that is more effective than the available vaccines. *Id.* ¶ 26, 30. It is of no help to him that he refers to Earth Tea as a "Natural Supplement Drink" in his motion. Rule 12 Mot. at 2; *see Nat'l Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977) ("In determining whether an article is a 'drug' . . . the FDA is not bound by the manufacturer's subjective claims of intent."); *United States v. Berst*, No. 6:11-cv-6370, 2012 WL 4361408, at *5 (D. Or. Aug. 2, 2012), *report and recommendation adopted*, No. 6:11-CV-6370-TC, 2012 WL 4361559 (D. Or. Sept. 20, 2012) ("[I]t is the claims defendant makes about his products, not the products themselves, which makes them drugs under the FDCA.").

Succinctly, because defendant promotes Earth Tea as a treatment or cure for a disease

(COVID-19), it is subject to the FDCA.[4] *See United States v. Writers & Research, Inc.*, 113 F.3d 8, 11 (2d Cir. 1997) (finding drug to be subject to requirements of the FDCA where it was "promoted as a treatment or cure for cancer, AIDS, or other diseases"). As a result, it is more than abundantly clear that the government has sufficiently pleaded that Earth Tea is a drug under the FDCA, and the motion to dismiss those claims must be denied.

II. Applicability of DSHEA

Construed deferentially, the second of Sinclair's two motion filings, at its crux, contends that his tea is subject to DSHEA and its higher pleading standard. Rule 11 Mot. at 2. His contention is without merit. It is true that Congress amended the FDCA in 1994 by enacting DSHEA, "which established a new regulatory category for dietary supplements," in order to "'narrow the reach of the FDA's preauthorization scheme out of concern over excessive regulation of dietary supplements and the suppression of truthful information.'" *United States v. Lane Labs-USA, Inc.*, 324 F. Supp. 2d 547, 564 (D.N.J. 2004) (quoting *Nutritional Health All. v. Shalala*, 144 F.3d 220, 224 (2d Cir. 1998)). DSHEA thus "expanded the types of claims dietary supplement manufacturers are permitted to place on their products without first obtaining approval from the FDA." *Id.*; *see also Jovel v. i-Health, Inc.*, No. 12-cv-5614 (JG), 2013 WL 5437065, at *4 (E.D.N.Y. Sept. 27, 2013). Still, the DSHEA "expressly prohibits claims that dietary supplements can 'diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.' In other words, DSHEA did not amend the FDCA's definition of 'drug.'" *Berst*, 2012 WL 4361408, at *7

[4] Indeed, even if Earth Tea did qualify as a dietary supplement, such classification does not preclude it from also meeting the definition of a drug under the FDCA. *See United States v. Ten Cartons, More or Less, of an Article Ener-B Vitamin B-12*, 72 F.3d 285, 287 (2d Cir. 1995) ("[E]ven if Ener-B were to qualify as a dietary supplement . . . that status would not be relevant to the determination whether Ener-B is a drug.").

(internal citations omitted); *see also Lane Labs-USA*, 144 F. Supp. 2d at 566 (holding DSHEA inapplicable to product that fell under FDCA's drug classification, because the defendant, "through its promotional material and even its employees, promoted [the product] for the diagnosis, cure, mitigation, treatment, or prevention of diseases"). As already discussed, the United States sufficiently alleged that Earth Tea falls within the FDCA's definition of a drug. *See supra* at 5–6. The burden of proof under the DSHEA is therefore inapplicable to a Rule 12(b)(6) analysis of the sufficiency of the government's pleading in this case.

Sinclair's language, in advancing this motion, suggests that the government's pleading should be faulted for not proving its claims. Rule 11 Mot. at 2. Such proof is not required to defeat such a motion. *Special & Superior Officers Benev. Ass'n ex rel. Sciascia v. Rochdale Vill., Inc.*, No. 11-CV-1580 JS WDW, 2012 WL 959790, at *5 (E.D.N.Y. Mar. 19, 2012) ("[O]n a motion to dismiss, Plaintiffs are only required to plead, not prove, facts sufficient to support a claim.").

III. Due Process

Linked to a grab-bag of constitutional and statutory authorities, the balance of Sinclair's motion rests on what is best discerned as a due process challenge to the government's claims. Yet, Sinclair fails to articulate any liberty or property interest of which he has been deprived. *See Sutera v. Transp. Sec. Admin.*, 708 F. Supp. 2d 304, 313 (E.D.N.Y. 2010) ("To prevail on either a procedural or substantive due process claim, a claimant must establish that he possessed a liberty or property interest of which the defendants deprived him."); *see also Berst*, 2012 WL 4361408, at *8 (rejecting defendant's argument that suit under FDCA violated due process, because "defendant has not established the existence of a liberty interest to work as a master herbalist"). And defendant cannot contend that the government is infringing on his right to sell Earth Tea by

bringing the instant suit, since "the government is not preventing defendant from selling [his product]. Instead, it is preventing him from selling [his product] with labeling claims that cause the products to be drugs under the FDCA without having the labeling claims evaluated by the FDA." *Berst*, 2012 WL 4361408, at *8.[5]

Conclusion

For the foregoing reasons, defendant's motion to dismiss is denied in its entirety.

The parties are directed to contact United States Magistrate Judge Robert M. Levy to set a conference for further pretrial management of this case.

So Ordered.

Dated: Brooklyn, New York
December 6, 2023

/s/ Eric N. Vitaliano
ERIC N. VITALIANO
United States District Judge

[5] Sinclair's invocation of the Fourteenth Amendment likewise fails—the Fourteenth Amendment "applies to the states but not to the federal government," and thus has no application here. *Doe v. Merck & Co., Inc.*, 803 F. App'x 559, 561 (2d. Cir. 2020). So too for Sinclair's request that the Court "uphold" the NYCFA, which imposes liability on one who knowingly makes a false claim to the government seeking payment from the treasury. *State v. MedImmune, Inc.*, 342 F. Supp. 3d 544, 551 (S.D.N.Y. 2018) (quoting U*nited States v. N. Adult Daily Health Care Ctr.*, 205 F. Supp. 3d 276, 287 (E.D.N.Y. 2016)).